UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,445	06/22/2006	Elie Leverd	3493-0170PUS1	4148

2292 7590 09/03/2009

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
09/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,445	LEVERD ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-16* is/are pending in the application.

4a) Of the above claim(s) *10,12 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/26/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/26/2009 has been entered.

Election/Restrictions

2. This application contains claims 10, 12 and 16 drawn to an invention nonelected with traverse in the reply filed on 1/28/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

3. Applicants' arguments, filed 6/26/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

4. Applicant's arguments, see p. 3, filed 6/26/2009, with respect to the drawing objection have been fully considered and are persuasive. The objection of the drawing has been withdrawn.

5. Applicant's arguments with respect to the rejection of claims 1-3, 7, 9 and 13 under 25 USC 103 have been fully considered but they are not persuasive:

Claims 1-3, 7, 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over GlaxoSmithKline ("Prescribing Information: Navelbine (vinorelbine tartrate) Injection: 2002 Nov; pp. 1-17; IDS 1/22/2008 reference CA) and Duflos et al. (US 6,127,377; 2000; IDS 10/4/2006 reference AB).

The rejection is maintained for the reasons of record.

6. Applicant's arguments with respect to the rejection of Claims 1-2, 4-7, 9 and 13 under 35 USC 103 have been fully considered but they are not persuasive:

Claims 1-2, 4-7, 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolgemuth (CA-2,001,643; 1990; IDS 10/4/2006 reference BC) and Duflos et al. (US 6,127,377; 2000; IDS 10/4/2006 reference AB).

The rejection is maintained for the reason of record.

7. Applicant's arguments with respect to the rejection of claims 8 and 14-15 under 35 USC 103 have been fully considered but they are not persuasive:

Claims 8 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over GlaxoSmithKline ("Prescribing Information: Navelbine (vinorelbine tartrate) Injection: 2002 Nov; pp. 1-17; IDS 1/22/2008 reference CA); Duflos et al. (US 6,127,377; 2000; IDS 10/4/2006 reference AB); and Wolgemuth (CA-2,001,643; 1990; IDS 10/4/2006 reference BC) as applied to claims 1-3, 7, 9 and 13; and 1-2, 4-7, 9 and 13 above, and further in view of Howell et al. ("Anti-vascular effects of vinflunine in the

MAC 15A transplantable adenocarcinoma model"; 2001; British Journal of Cancer; 84(2): 209-295; IDS 10/4/2006 reference CG).

The rejection is maintained for the reasons of record.

8. Applicant's only arguments with respect to any of the above rejections is to state that a declaration under 37 CRF 1.132 will be filed in the future. Consideration of the statements made in the Leverd Declaration, filed 7/21/2009, is made as follows:

Applicant argues improved stability of the composition in connection with Examples 1 and 2 of the specification. The comparison is between vinflunine ditartrate in pulverulent form with that of vinflunine ditartrate in aqueous solution. Such a comparison, while interesting, does not demonstrate a comparison relevant to establishing unexpected results over the closest prior art used in the above rejections. The first rejection above is based on a teaching of an aqueous solution of a related compound to vinflunine ditartrate, i.e., vinorelbine tartrate, in the same type of aqueous solution as the instant claims, not in pulvirulent form; the relationship between vinorelbine and vinflunine motivates the substitution of one for the other in the same type of aqueous solution.

Applicant further argues that the above-noted advantageous properties were not conventionally recognized. While they may not have been recognized by the references cited by applicant, the above combination of references does obviate the type of solutions claimed; and recognizes the usefulness of solutions of the exact type as claimed in the instant application.

Applicant argues there are significant distinctions between vinflunine and vinorelbine; there are significantly different physico-chemical properties: 1) in water solubility is different. It is not clear how this would affect the stability of one vs. the other, which would be required to demonstrate some unexpected property of the claimed composition over the combination of references. There is no evidence of record that compound of the type claimed have any correlation between solubility and stability. 2) Different properties are exhibited by each in the form of a powder after 6 months; different major impurities are formed; data for one of the impurities has been presented as a function of different conditions. First, this is not directly relevant to the claimed compositions, which are in solution form; secondly, there is only data for the degradation kinetics for one compound; since the rejections of record are based on the substitution of one art-recognized compound for another, evidence of unexpectedly superior stability of the vinflunine composition should demonstrate better degradation kinetics for vinflunine ditartrate solutions than for solutions containing the other compounds the rejections are based on, such as vinorelbine ditartrate. 3) The process for manufacturing vinflunine is totally different from the process for manufacturing vinorelbine. This is not relevant to a demonstration of some unexpected stability over another prior art solution. 4) Vinorelbine exhibits fungicidal activity after up to 28 days of contact with mold spores, whereas vinflunine exhibits no fungicidal activity. While this could be important to stability, no such evidence has been presented, nor has a demonstration that such differences in activity would lead to an unexpected better stability of the claimed compound over the combination of prior art references.

Applicant argues that vinflunine generally appears to be less stable than vinorelbine since it has lower solubility; it is not clear what the basis for this argument is; stability and solubility are not the same; and there is no evidence of record that they are somehow correlated.

The argument that differences somehow would lead to the conclusion that it would not be predictable to employ one compound in place of another, with an expectation of improved storage stability is not persuasive. As pointed out in MPEP 2143 B, Example 2, "obviousness does not require absolute predictability of success." *In re O'Farrell* at 903, 7 USPQ2d at 1681. For the reasons of record, there would have been a reasonable expectation of similar stability when substituting one compound for another, based on the stability of at least two aqueous formulations, of record, and the similar structures of the compounds being substituted.

Therefore the rejections are maintained.

Conclusion

9. No claim is allowed.

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614